

Appl. No. : **10/616,102**
Filed : **July 9, 2003**

REMARKS

Upon entry of the foregoing amendment, Claims 1-26 remain pending in the above-identified application. Claims 1, 9, 16 and 23 have been amended. New Claims 24-26 have been added.

Objection to the Claims

Claim 23 stands objected to under 35 C.F.R. § 1.75(c), as being an improper dependent claim for failing to further limit the subject matter of the parent claim. Applicants have amended Claim 23 to depend from newly added Claim 26. Applicants respectfully request withdrawal of this objection.

Rejection of the Claims Under 35 USC § 102

Claims 1, 2, 5, 6, 16, 18, 19 and 22 stand rejected under 35 USC § 102(b) as being anticipated by D'Antonio (U.S. Patent No. 5,810,831). Applicants have amended Claims 1 and 16.

D'Antonio discloses a femoral sizing guide having a sizing guide block 22 that can be positioned adjacent a distal end 16 of a femur 10, from which a distal portion 14 has been removed. See '831 patent at Col. 4, lines 1-10. The guide also has separate locator feet 26 for engaging the posterior condyles 30 to assist in the location of a femoral cutting guide of suitable size. See '831 patent at Col. 4, lines 18-42; Figure 1. The guide block 22 has drill guide openings 60 to guide a drill 62, "thereby assuring the appropriate subsequent location of the femoral cutting guide on the distal femur." '831 patent at Col. 4, lines 57-62. The locator feet 26 can be chosen from a variety of sizes, and are removably coupled to the guide block 22 to "space the openings 60 in the sizing guide block 22, in the anterior/posterior direction, by a corresponding selected amount." '831 patent at Col. 5, lines 12-35. The surgeon can therefore interoperatively change the locator feet 26 to change the femoral sizing guide dimensions. '831 patent at Col. 2, lines 15-30; col. 5, lines 12-42.

However, D'Antonio does not disclose, teach or suggest, among other things, a "pre-determined distance defined by a template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and flank defined as a single piece," as recited in amended Claim 1. In contrast, as described above, the femoral sizing guide of D'Antonio has separate removable and replaceable locator feet that the

surgeon can change interoperatively (or during a surgical procedure). Accordingly, Applicants respectfully submit that amended Claim 1 is allowable over D'Antonio.

Similarly, Applicants have amended Claim 16 to recite, among other limitations, a "femur-size template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and the flank defined as a single piece," which Applicants respectfully submit is not disclosed in D'Antonio, as discussed above with respect to Claim 1.

Furthermore, as discussed at the recent interview, D'Antonio fails to teach or suggest the undersizing of the femoral slideway relative to the unresected femur, as recited in amended Claims 1 and 16.

Figure 4 of Applicant's specification illustrates one non-limiting embodiment, reproduced below, wherein a femur-size template is used to locate the previously-determined distance "e" from a peg-hole and condyles of an unresected femoral bone.

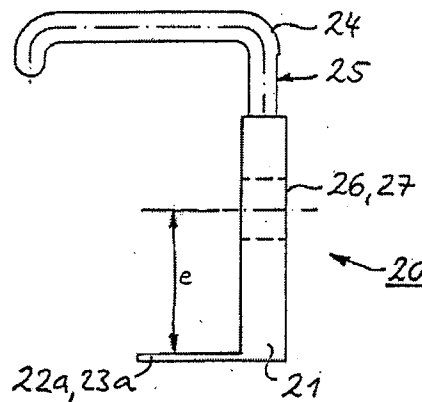
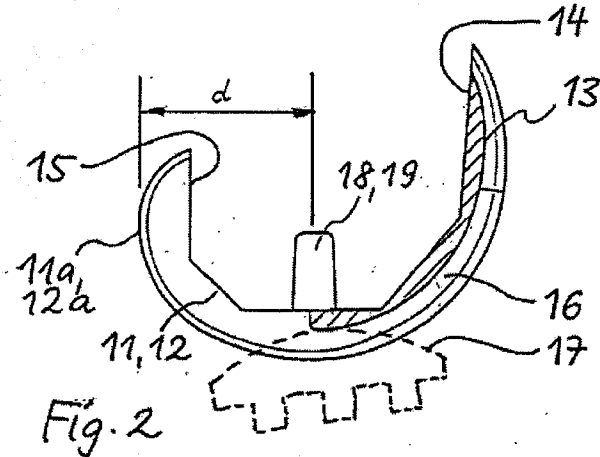


Fig. 4

The femur-size template (20) has a basic or support part 21 and contact surfaces or flanks (22a, 23a), with a bore (26, 27) extending through the support part (21) at a previously determined distance "e" from the contact surfaces (22a, 23a). Once the peg-hole is drilled through the bore (26, 27) while the support part (21) and contact surfaces (22a, 23a) of the template engage the unresected condyles of the femur, a slideway, such as shown in Figure 2, is selected, which has a distance "d" defined between the outermost posterior points on the distal sliding surfaces (11a, 12a) and the long axis of the pegs (18, 19). The distance "e" between the bores (26, 27) and the contact surfaces (22a, 23a) is not adjustable (i.e. the support part (21) and

flanks (22a, 23a) are a single piece), nor are the contact surfaces (22a, 23a) detachable from the femur-size template or adjustable to accommodate variations in femur anatomy.



This slideway is selected such that the distance “e” is greater than the distance “d”, indicating that more bone has been resected dorsally on the femur than will be replaced by the thickness of the dorsal parts of the condyle shells, as shown in Figure 5b below. As described in the non-limiting embodiment on page 2, line 29 – page 3, line 9 of the specification, the distance “e” can be greater than the distance “d” by 5-15%, and in particular by about 10%. Moreover, because the peg-hole location was predetermined by use of the femur-size template, the slideway’s position is also predetermined relative to the original, unresected femur.

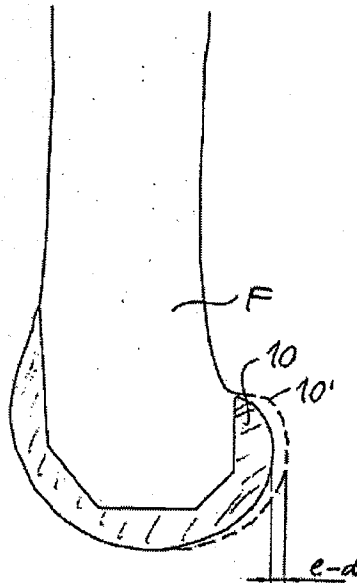


Fig. 56

Accordingly, Applicants respectfully submit that amended Claims 1 and 16 are allowable over D'Antonio. Claims 2, 5, 6 and 22 depend from amended Claim 1 and are therefore also allowable over D'Antonio for at least the same reasons as amended Claim 1. Claims 18 and 19 depend from Claim 16 and are therefore also allowable over D'Antonio for at least the same reasons as Claim 16.

Rejection of the Claims Under 35 USC § 103

Rejections in view of D'Antonio

Claims 3, 4, 7, 9-15, 17, 20, 21 and 23 stand rejected under 35 USC § 103(a) as being unpatentable over D'Antonio. Applicants have amended Claims 9 and 23.

Claims 3, 4 and 7

Applicants respectfully submit that amended Claim 1 is patentable over D'Antonio because D'Antonio does not teach or suggest, among other things, a "template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and flank defined as a single piece," as recited, among other limitations, in amended Claim 1. As discussed above, D'Antonio instead discloses a sizing guide block 22 with interchangeable locator feet 26 of different sizes, and notes that the surgeon can interoperatively change the locator feet 26 to change the femoral sizing guide dimensions. '831 patent at Col. 2, lines 15-30; col. 5, lines 12-42. Claims 3, 4 and 7 depend from amended Claim

Appl. No. : 10/616,102
Filed : July 9, 2003

1 and are therefore also patentable over D'Antonio, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught in the cited art.

Claims 9-15

Applicants respectfully submit that D'Antonio does not disclose, teach or suggest, among other things, "resecting bone material from said femur, wherein said resecting includes removing more bone material from a dorsal side of the femur than will be replaced by the slideway to allow for a reduction of the distance between the peg and a center of the turning radius of the dorsal portion of the slideway compared to the unresected femur to reduce a load on ligaments attached to the femur," as recited, among other limitations, in amended Claim 9 and discussed above. Moreover, D'Antonio does not disclose "indicating a point at a previously-determined distance from a dorsal most point of said femur, wherein said previously-determined distance is 5 to 15% larger than a distance between a peg and a dorsal sliding surface of the femoral slideway to be implanted on the femur bone," as recited, among other limitations, in amended Claim 9.

Applicants respectfully submit that a rejection based on "optimum or workable ranges" is inappropriate where the prior art does not teach or suggest the desirability of the result achieved. As discussed in MPEP § 2144.05, "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." In re Antonie, 559 F.2d 618, 195 U.S.P.Q. 6 (CCPA 1977). Thus, for a rejection to be made based on "optimum or workable ranges," the prior art must first identify the result which the variable achieves. Without D'Antonio teaching the desired results of reducing the distance between the peg and center of the turning radius of the dorsal portion of the slideway in order to reduce a load on ligaments attached to the femur, it would not have been merely a matter of design choice, as the Examiner suggests, for the previously-determined distance to be 5 to 15% larger than a distance between a peg and a dorsal sliding surface of the femoral slideway.

D'Antonio fails to teach or suggest the unique features described above, and in particular, those recited in amended Claim 9. For the reasons discussed above, Applicants respectfully submit that amended Claim 9 is patentable over D'Antonio. Claims 10-15 depend from amended Claim 9 and are therefore likewise patentable over D'Antonio, not only because they depend

Appl. No. : 10/616,102
Filed : July 9, 2003

from an allowable base claim, but also because each of these claims recites a unique combination of features not taught in the cited art.

Claims 17, 20 and 21

Applicants respectfully submit that amended Claim 16 is patentable over D'Antonio because D'Antonio does not teach or suggest, among other things, "resecting bone material from a femur, wherein said resecting includes removing more bone material from a dorsal side of the femur than is replaced by the slideway," as recited, among other limitations, in amended Claim 16. Additionally, Applicants respectfully submit that D'Antonio does not teach or suggest, among other things, "a femur-size template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and the flank defined as a single piece," as recited, among other limitations, in amended Claim 16. As discussed above, D'Antonio discloses a sizing template with a plurality of removable locator feet (26) interchangeable interoperatively by the surgeon and that define a variable distance between the contact surface of the locator feet and the bores on the sizing template. In contrast, as illustrated in the non-limiting embodiment of Figure 4, reproduced above, the distance between the bore (26, 27) and the contact surface (22a, 23a) on the femur-size template is not adjustable and the support part (21) and contact surface or flank (22a, 23a) are a single piece. Additionally, the femur-size template shown in Figure 4 does not allow for the compensation of variations in femur anatomy since the contact surfaces (22a, 23a) are not detachable from the femur-size template.

Claims 17, 20 and 21, depend from amended Claim 16 and are therefore also patentable over D'Antonio, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught in the cited art.

Claims 23

Applicants have amended Claim 23 to depend from new Claim 26, which recites, among other limitations, a method of preparing a lower extremity of a femur and implanting a femoral slideway thereon, the method comprising "a template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and flank permanently connected to each other." Applicants respectfully submit that D'Antonio does not disclose, teach or suggest the method in Claim 26. Instead, as discussed above,

Appl. No. : 10/616,102
Filed : July 9, 2003

D'Antonio discloses a sizing template with a plurality of removable locator feet (26) interchangeable interoperatively (i.e., not permanently connected) by the surgeon and that define a variable distance between the contact surface of the locator feet and the bores on the sizing template. Accordingly, Applicants respectfully submit that new Claim 26 is patentable over D'Antonio. Claim 23 depends from Claim 26 and is therefore likewise patentable over D'Antonio, not only because it depends from an allowable base claim, but also because it recites a unique combination of features not taught in the cited art.

Rejection in view of D'Antonio and Colleran

Claim 8

Claim 8 stands rejected under 35 USC § 103(a) as being unpatentable over D'Antonio in view of Colleran (U.S. Pat. No. 5,776,201). Applicants respectfully traverse this rejection.

As discussed above, Applicants respectfully submit that amended Claim 1 is patentable over D'Antonio because D'Antonio does not teach or suggest, among other things, a “pre-determined distance defined by a template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and flank functioning as a single piece during use, the contact surface configured to engage at least one of the dorsalmost points of the lateral and medial condyles of the femur,” as recited in amended Claim 1.

Claim 8 depends from Claim 1 and is therefore likewise patentable over D'Antonio, alone or in combination with the cited references, not only because it depends from an allowable base claim, but also because it recites a unique combination of features not taught in the cited art. For example, Claim 8 recites, among other limitations, that “**all** of the slideways in said group have **substantially equal peg-to-sliding surface dimensions** as defined by a perpendicular distance between a longitudinal axis of a peg extending from the slideway and a plane tangent to a dorsal sliding surface furthest away from the peg, each slideway in said group has a different dorsal condyle-to-ventral condyle distance.” Colleran, alone or in combination with D'Antonio, fails to teach these features. In particular, Colleran at most teaches femoral implants with different anterior-posterior lengths, not peg-to-sliding surface lengths. See Colleran, Col. 2, lines 54-67. However, Colleran does not teach or suggest a group of slideways, wherein **all** of the slideways in the group have **substantially equal peg-to-sliding surface dimensions**, each slideway in said

Appl. No. : 10/616,102
Filed : July 9, 2003

group having a different dorsal condyle-to-ventral condyle distance. The peg-to-sliding surface dimension is illustrated in the non-limiting embodiment shown in Figure 2 of Applicant's specification as a distance "d," whereas the dorsal condyle-to-ventral condyle distance is illustrated in the non-limiting embodiment shown in Figure 1 of Applicant's specification as a distance "a."

New Claims 24 and 25

Applicants have added new Claims 24 and 25, which Applicants respectfully submit are allowable over D'Antonio. Claim 24 recites, among other limitations, "a template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and flank functioning as a single piece during use." Claim 25 recites, among other limitations, "a femur-size template having a permanently specified distance between a bore on a support part and a contact surface on a flank of the template, the support part and the flank functioning as a single piece during use." As discussed above, the sizing guide in D'Antonio consists of a block (22) and removable and interchangeable locator feet (26). Therefore D'Antonio does not disclose or teach, among other things, a template with a support part and a flank functioning as a single piece during use. Accordingly, Applicants respectfully submit new Claims 24 and 25 are allowable over D'Antonio.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Applicants also have not presented arguments concerning whether the applied references can be properly combined in view of the clearly missing elements noted above, and Applicants reserve the right to later contest whether a proper motivation and suggestion exists to combine these references.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped

Appl. No. : 10/616,102
Filed : July 9, 2003

issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney in order to resolve such issue promptly.


Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Nov. 20, 2006

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AMEND

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